ev3 Your endovascular company.

510(k) Summary

NanoCross™ Elite 0.014" Over-the-Wire PTA Balloon Dilatation Catheter

510(k) Summary	This 510(k) summary information is submitted in accordance with the requirements of 21 CFR §807.92.
Applicant	ev3 Inc.
Submitter	ev3 Inc. 3033 Campus Drive Plymouth, MN 55441-2651 SEP 2 6 2013 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Laura J. Lind
Date Prepared	July 22, 2013
Device Trade Name	NanoCross™ Elite 0.014" Over-the-Wire PTA Balloon Dilatation Catheter
Device Common Name	PTA Dilatation Catheter
Classification Name	Catheter, Angioplasty, Peripheral, Transluminal (21 CFR §870.1250, Product Code LIT)
Classification Panel	Cardiovascular
Predicate Devices	NanoCross™ .014" OTW PTA Dilatation Catheter (K082854, K090849), RapidCross™ PTA Rapid Exchange Balloon Dilatation Catheter (K130911).
Intended use	The NanoCross™ Elite 0.014" Over-the-Wire PTA Balloon Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.
Device Description	The NanoCross catheter is an over-the-wire (OTW) coaxial lumen percutaneous transluminal angioplasty (PTA) balloon catheter compatible with 0.014"guidewires with a distally mounted semi-compliant inflatable balloon and an atraumatic tapered tip. The distal portion of the catheter has a lubricious coating. The manifold includes a lumen marked "THRU". This is the central lumen of the catheter, which terminates at the distal

tip. This lumen is used to pass the catheter over a guidewire with a maximum diameter of 0.014". The lumen marked "BALLOON" is the balloon inflation lumen, which is used to inflate and deflate the dilatation balloon with a mixture of contrast medium and saline solution. The balloon has two radiopaque markers for positioning the balloon relative to the stenosis. The radiopaque marker bands indicate the dilating or working section of the balloon.

The NanoCross Elite catheter is available in balloon sizes ranging from 1.5 mm to 4 mm in diameter, and from 20 mm to 210 mm in length; reference labeling for introducer sheath compatibility.

Performance data

Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.

Using internal Risk Analysis procedures, the following tests were performed for one or more model sizes:

• Balloon Dimensional Verification	• Catheter Dimensional Verification
• Balloon Rated Burst Pressure (Unconstrained and In Stent)	• Balloon Fatigue (Unconstrained and In Stent)
• Balloon Compliance	• Inflation/Deflation Time
• Catheter Bond Strength	• Kink
• Device Tracking	• Insertion Force
• Balloon Pull-back Force	• Torque Strength
• Radiopacity	• Presence of Coating
• Re-Insertion Force	• Pushability

Using the same Risk Analysis procedures, the following tests were leveraged from predicate devices for one or more model sizes:

• Balloon Dimensional Verification	• Balloon Rated Burst Pressure (Unconstrained and In Stent)
• Balloon Fatigue (Unconstrained and In Stent)	• Balloon Compliance
• Coating Durability	• Particle Generation

The device was tested for biocompatibility per ISO 10993-1 for short duration contact with blood (<24 hours). The testing included cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemolysis, pyrogen, complement activation, thromboresistance, partial thromboplastin time, and platelet/leukocyte count.

The NanoCross Elite catheter met all acceptance criteria for the

	bench testing with results similar to the predicates. Based on the bench test results, comparison to legally marketed predicates, and non-clinical test results, the NanoCross Elite catheter is determined to perform as safely and effectively as the predicates for its intended use.
Summary of Substantial Equivalence	The NanoCross Elite catheter has the following similarities to the predicate devices: • Similar fundamental scientific technology • Same intended use • Similar operating principle • Identical balloon rated burst pressures • Similar balloon nominal pressure • Similar balloon diameters • Similar balloon lengths • Similar catheter lengths • A lubricious coating • Same cleanroom and shared manufacturing lines • Same sterility assurance level and sterilization method All devices are compatible with 0.014" wires and 4F sheaths. All devices have similar construction and principles of operation. All devices are used by the physician in a similar manner typical of PTA balloon catheters. The NanoCross Elite catheter and the predicates have the same intended use - all devices are intended to treat peripheral arteries. All devices are intended to treat the same target population. The manner in accessing and treating lesions is similar for the devices. The indications for use are identical to the RapidCross™ Catheter.
Conclusion	Based on the intended use, technological characteristics, and results from safety and performance testing, the NanoCross™ Elite 0.014" Over-the-Wire PTA Balloon Dilatation Catheter is considered substantially equivalent to the legally marketed predicate devices NanoCross™ .014" OTW PTA Balloon Dilatation Catheter (K082854, K090849) and RapidCross™ PTA Rapid Exchange Balloon Dilatation Catheter (K130911).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 26, 2013

ev3, Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K132777
Trade/Device Name: NanoCross™ Elite 0.014" Over-the-Wire PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: September 4, 2013
Received: September 5, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Todd D. Courtney -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132777

Device Name: NanoCross™ Elite 0.014" Over-the-Wire PTA Balloon Dilatation Catheter

Indications for Use:

The NanoCross™ Elite 0.014" Over-the-Wire PTA Balloon Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Todd D. Courtney -S